Internal Quality System Audit
Summary and Report

Internal QSA Dates

Description	Date(s)
Internal Audit Main Event (1-2 weeks)	March – December 2016
Internal Audit Main Event Closing Meeting	*NA
Report Submit to CRL Directors	January 27, 2017

*Note: Internal audit Main Event Closing Meeting does not apply to this QSA since the CRL QA Coordinator (with some assistance) performed the entire audit. Management is notified of all audit findings through the monthly QA-Management monthly meetings. CRL staff members will be notified with a summary of the audit in the Feb 2017 QA-Groups monthly meeting. Individuals (observed analysts) participating in the audit were notified of any findings as they were discovered.

Internal QSA Team Information

Title	Audit Function	Name	Position	Experience
Lead Assessor	ISO 17025, Section 4, Reviews, Reports	Angela Ockrassa Davis	QA Coordinator	Internal system and SOP audits
Assessor 1	ISO 17025: 2002 Section 5	Angela Ockrassa Davis	QA Coordinator	ISO/IEC 17025 Internal Audit training
Assessor 2	ILAC G19: 2002 Forensic Science	Angela Ockrassa Davis	QA Coordinator	Same as above
Assessor 3	SOP Activity	Angela Ockrassa	QA Coordinator	Same as above
	Witnessing SOP activity	Robert Thompson	Organic Chemist	Overseen by QAC

Acronyms and Definitions

Comment: A finding about documents or practices with a potential of improvement; but still fulfilling the requirements. Any comments found during this audit are summarized at the end of this report.

Concern: A finding where, in the opinion of the audit team, the practice may develop into a noncompliance or nonconformity. Any concerns discovered during this audit are summarized following this section.

Finding: An audit conclusion referenced to a requirement and supported by objective evidence that identifies compliance with and/or a deviation from the requirement. NOTE: Lack of evidence identifying compliance with a requirement is a finding.

Non-compliance: A finding where the documents or practices do not meet the requirements of the ISO 17025 standards, the SOPs, the QMP, or other regulatory programs in a way that jeopardizes the quality of work. Any found non-compliances during this audit are summarized following this section.

Non-conformance: A finding that lacks in characteristic, documentation or procedure rendering the quality of the item or activity unacceptable. A technical finding can be a type of non-conformance. Any non-conformances discovered during this audit are summarized following this sections.

Internal Audit Summary

	Audit Description	Y/N	[1]Finding(s)	[2]Workflow ID(s)	Comment
1	Were previous year CA(s) implementation and/or effectiveness confirmed?	Y	0	NA	
2	Was CRL checklist 004-A, Internal system audit for ISO 17025 components, completed?	Y	2	9287	2 Non-compliances 2 Concerns 10 Comments
3	Was CRL checklist 004-B, Internal system audit for ILAC G-19 (CIS) components, completed?	Y	0	NA	3 comments
4	Was CRL checklist 004-C, Internal SOP activity audit(s) for witnessing, completed?	Y	7	*Note	7 non-compliances 3 concerns 4 comments
5	Follow up audit recommended/scheduled?	N	--	--	**MS026 note
6	Total number of deficiency findings	9	--		--
7	Total number of non-deficiency findings	5			--

*Note (workflow): All workflow instances (CA, PA, Task) initiated for SOP activity audit are documented in their respective SOP audit report (location: Qualtrax/Documents/Quality Assurance/QAC/Audits/SOP Activity Audits/2016.

** (MS026): One the technical data review for MS026 is available, it will be completed and any findings attached as an appendix file to this document in Qualtrax.

Report Description

Table line item #2 - ISO 17025

Findings:

(1) Noncompliance 01 – ISO 17025 section 4.15.1 states that the management review shall include a review of the Overall Objectives from ISO section 4.2.2. The 2015 Annual Management Review (AMR) minutes do not include the review of the overall objectives by management. The QA Coordinator remembers that it was however discussed, just not documented. Recommendation: Create a checklist for annual management review to standardize agenda items so that documentation does not get missed.

(2) Noncompliance 02 – ISO 17025 section 4.13.1.4 states that there should be procedures in place to protect and back-up electronic records and prevent unauthorized access. There appears to be an undocumented policy in practice regarding the protection of computers (and essentially technical records) associated with analytical instruments in the working laboratory area (not admin area). This policy does not allow IMB updates to be performed which means that internet accessible on such computers is also not possible, unless approved by management on a case by case basis. Recommendation: Include this policy in the QMP.

(3) CONCERN 01 – ISO 17025 section 5.46.3.4 states that there must be procedures for safe handling, transport, and use of reference standards and materials. While the lab has procedure documented in the

[1] State the number of finding(s) base on deficiencies unless otherwise specified.
[2] Qualtrax workflow IDs: CAR, PA, or Task (Request)

chemical hygiene plan for safety handling and analytical SOPs have instructions for the use of reference standards and materials, there does not appear to be any documentation regarding transport. (examples transporting acids). Recommendation: Edit GEN026 to including the missing instructions.

(4) CONCERN 02 – ISO 17025 section 5.10.3.2 a)-c) state testing report requirements for sampling information. QMP v4 does not address these requirements, even though QMP v3 did. Apparently they dropped out from one version to the next. Recommendation: Update the QMP to include the missing information.

Comments: (Mostly suggestions for QMP clarifications and/or citation)

1. ISO 17025 section 4.8 states that policies and procedures exist for handling client complaints. Although the CRL QMP does provide a procedure, the definition of a client 'complaint' is not defined leaving the process open to interpretation. Recommendation: Define client complaint.
2. ISO 17025 section 5.5.7 requires the lab to examine the effect of the defect or departure on previous testing equipment (including supportive equipment) and initiate "Control of nonconforming work" procedures. Although this requirement is met with the NCR policy, I recommend linking or referencing the nonconforming work (NCR) procedure in the SE section of the QMP for incidents when the SE gives suspect results, is overloaded, mishandled or shown to be defective or outside specified recertified limits. In addition, add a note that for this type of NCR, instructions should be included for the item to be removed from circulation/use and the lab shall examine the effect of the defect or departure form specified limits on previous tests.
3. ISO 17025 section 5.5.8 states that equipment shall be labeled, coded or otherwise identified to indicate status of calibration, including date calibrated, and date or expiration criteria when calibration is due. In the QMP under the SE section, state that whenever practical, SE shall be labeled to identify when it was last certified and when it is due or expiration date. This information is currently not present.
4. ISO 17025 section 5.5.9 states that if equipment goes outside the control of the lab, it shall be proven that the function and calibration status are satisfactory before being returned to service. Not addressed in QMP v3, but QMP v4 section 5.2 addresses it. Recommend specifying 'supportive equipment' in the statement and maybe include the procedure to send it out for 3rd party recertification.
5. ISO 17025 section 5.8.2 states that samples must be identified and identity retained throughout life of item in lab. Currently he QMP does not specify that the ID is retained for the life of the item.
6. ISO 17025 section 5.9 c) stat that assurance in the quality of sample results should include replicate t/c using same or different methods. Currently the QMP does not address this requirement, even though it does not apply unless the client requests such action.
7. ISO 17025 section 5.10.2 a) – k) state the requirements for test reports. Many of the details meeting the test report requirements could better be addressed in QA-WI005 by elaborating or listing a requirement rather than referencing a sample report. See CHKLST 004A page 23-24 for detailed requirements.
8. ISO 17025 section 5.10.3 a) and b) states test report requirements for interpretation. The requirements are better placed in QA-WI005 (data packages/reports) instead of QA-WI006 (case narratives).
9. ISO 17025 section 5.10.7 states that results transmitted by telephone, telex, fax, or other electronic or electromagnetic means shall follow the requirements of 17025. PDF reports do not match EDD information. Clarify in the QMP that EDDs, PDF, WO must always go out together [final data], otherwise it may not meet this standard. Alternatively, or in addition, include a disclaimer in the QMP quoting ISO section 5.10.1 3rd paragraph.
10. ISO 17025 section 5.10.9 states that amendment reports shall meet the requirements of 17025. ISO Currently the QMP does not state this requirement even though it is being met. All CRL PDF reports meet ISO 17025 requirements so when a report is regenerated, the same standard report format is used therefore meeting this requirement. Recommendation: Specify in the QMP that amended reports meet the ISO requirements.

Table line item #3 – ILAC G19 (Forensics)

Comments: All comments suggest document revision to clarify or better explain how CRL meets the required standard(s).

1. ILAC G-19 section 5.2.6 states that laboratory personnel working in the laboratory shall be trained and retrained to remain qualified to perform the work. ILAC Comment 01: Since CRL does not receive samples from CID on a regular basis, the CID training should occur as needed and before working on sample for that year, not annual.
2. ILAC G-19 section 5.8.5 states that Laboratory shall be able to demonstrate that the items/samples examined and reported on were those submitted to the laboratory. ILAC Comment 02: QMP sections 9.9 should explain how we meet this standard. Currently, the process is referenced with sections 6.10.7, 8.4.1 in pieces but it should be explained better in section 9.9.
3. ILAC G-19 section 5.5.13.1 states that General Service Equipment not directly used for making measurements (e.g. hot plates, stirrers, non-volumetric glassware, cameras, refrigerators, thermal cyclers) shall be appropriately maintained. The checklist's current citation (GEN026 section 8.5.2) may not address this standard directly. Edit GEN026 to directly address the ILAC requirement.

Table line item #4 – SOP Audits

<u>AIG005 – Alkalinity (Technology: Electromagnetic)</u>

Comment 01: SOP AIG005 v3 section 9.10 states instructions to transfer the sample into the instrument sample cups, etc. The steps prior to this one discuss instrumentation, calibration, and buffers. There are no instructions stating that the sample must first be homogenized before pouring into the instrument sample cups. In the A&I group, all samples (except Ammonia soil) are homogenized before pouring and all of the group analyst have been observed to meet this practice. However, the written instruction to homogenize the sample is a required instruction that could affect sample results, should it ever be missed, and should be included in the SOP. Task #9280 has been initiated to include the missing step in the SOP.

<u>AIG009A – TOC (Technology: Combustion IR)</u>

No comments or findings.

<u>AIG034B – TP (Technology: Spectrophotometric)</u>

Noncompliance 01: The SOP section 9.1.9.2 step to check the heating block temperature was not performed during the witnessing audit. It missed the quarter marks, often and once went beyond a quarter without checking the heating block.

Noncompliance 02: The QMP v4 section 6.4.1.3 (policy 013-04) states Instrument electronic shall be archived on the CRL secure R5 CRL LAN "I" drive as soon as possible and according to each group's data verification or upload SOP. The pertinent data was analyzed 09/23/16, but not backed up to the "I" drive

until 10/03/16. Because the data was backed up 10 days later, and not as soon as possible, it is noncompliant to policy 013-04.

Concern 01: The SOP section 9.6.5 is missing a step to clear the instrument files once the data has been transferred to a USB (step 9.6.5.2) and then backed up to the server.

Comment 01: During the observed portion of the SOP audit, the analyst did not refer to the pertinent SOP even once. Recommendation: The analyst should look at the SOP when performing analysis. Even though she clearly knows the mechanics of the procedure, reviewing the SOP steps allows one to opportunity to capture missing steps, such as the ones noted above in line item #3 and #4.

AIG044E – Mercury (Technology: AA)

Comment 01: When dealing with concentrated acids, the analyst deviated from the chemical hygiene plan and did not wear an apron or face shield. Chemical hygiene plan states: When handling concentrated corrosives, acids or bases, 5 N and above, safety goggles or safety glasses with a face shield must be worn. Protective lab coats, aprons and sleeves or sleeved aprons are also required.

AIG045A – Anions by IC (Technology: Ion Chromatography)

Comment 01: The data review checklist uses “validation” language. This should have been adjusted per the QMP and CA 6577.

AIG048 – Flashpoint (Technology: Flashpoint)

Noncompliance 01: SOP AIG048A v3 section 9.5.5 (range finding), second sentence states “If no flash is observed, repeat at 9°F higher intervals until a flash is observed.” During the audit, one of the repeated intervals were observed to exceed the instructed 9°F internal by 1°F (95°F to 105°F). This point/range was not repeated; range finding continued to the next point. In the future, it is recommended that should this type of incident occur, the point/range be repeated [stop and cool the temp down] prior to continuation in order to comply with the SOP instructions. Although this deviation is not significant (range finding) since it did not flash at that range, it is still considered an SOP deviation against the reference method.

Comment 01: The balance used (Balance #21) still has standard weight acceptance criteria that is not in compliance with GEN026. CA #5745 was opened in 2015 regarding this issue and it is still not resolved. That being said, the current limits are tighter than those stated in GEN026 so no data is being affected by this incident, but the CA is over a year old and really should get resolved.

Metals003 – Metals (Technology: ICP)

Noncompliance 01 – During the SOP Metals003 v5 audit, the observed analyst was referencing an electronic copy of an SOP that was out of date. The analyst looking at SOP Metals003 v3 (published in May 2015); located on the desktop of the instrument (ICP-AES) computer. SOP Metals003 v5 is the current and correct version to reference. This incident does not comply with ISO 17025 section 4.3.2.2 concerning document control and availability which is covered under QMP v5 section 6.3 (policy 012) and 9.4.2.2. Policy 012 - All QA documents shall be controlled following the provided stipulations [in that section] which outline Qualtrax as the centralized location for all current QA documents. Section 9

Implementation of Work procedures (9.4 SOPs), specifically section 9.4.2.2 states that electronic SOPs are available in Qualtrax, the agency intranet, and temporarily in LIMS until it is determined that sufficient bench work stations in the laboratory have internet access.

Noncompliance 02 – The instrument's raw data (electronic records) for the WO 1610015 data were not present in the I drive. On 01/17/17. the QAC also asked the primary to locate it, but she could not find it either. This incident does not meet QMP v4 section 6.4.1.3 Policy 013-04 which states that "instrument electronic shall be archived on the CRL secure R5 CRL LAN "I" drive (\\204.46.201.26\Root Share\R5CRL) as soon as possible and according to each group's data verification or upload SOP which includes the group's naming convention." Recommendation: Place this check (data backed up) in the group's data review checklist.

GC030 – Oil and Grease (Technology: Gravimetric)

Noncompliance 01A: GC032 v5 section 9.5.3 states to "extract the sample by shaking the separatory funnel vigorously for 2 minutes with periodic venting into a hood to release excess pressure." The sample was shaken with periodic venting under a hood, but for less than one minute/per sample. Section 9.5.4 had a similar situation regarding the lack of tracking the time per procedural instruction, but discussed early enough during the procedural step so that better tracking could begin at that moment [once pointed out].

Noncompliance 01B [current practice not reflected on SOP]: (1) Food coloring was added after section 9.5.3 and before 9.5.4, but the SOP does not document this instruction. The adding of the food coloring is mentioned in section 9.6.1 however. (2) The observed analyst noted that section 9.6.3.1 second sentence ("Do not allow the bottom layer (water) to get into the pan.") and all of section 9.6.3.2 should be deleted from the SOP as it does not apply due to the upgraded instrumentation in use. (3) Section 9.3.1 is not reflecting current practice: According to GEN013 section 8.1.3.7, the analyst performs the pH verification procedure. (4) Also see General Info Notes above.

Noncompliance 01C: [SOP deviations against method reference] (1) The reference EPA method 1664B section 11.3.10 states "Rinse the tip of the separatory funnel, the filter paper, and the funnel with 2-3 small (3-5mL) portions of n-hexane. Collect the rinsing in the flask." This step is currently missing in the pertinent CRL SOP. (2) For the preparation of the spiking solution, the reference method section 7.10.3 NOTE states "If there is doubt of the concentration, remove 10.0 +/- 0.1mL with a volumetric pipet, place in a tared weighted pan, and evaporate to dryness in a fume hood." The Note on the pertinent CRL SOP section 7.2.4 states "Check the solution concentration by placing 5.0 mL of standard onto a weighed evaporating dish, dry and weigh out the residue." Both SOPs stat that the final weight should be 40.0 +/- 1mg, but the CRL deviates from the method reference regarding the volume (10mL vs. 5mL) of standard removed, including accuracy (+/- 0.1mL).
Recommendation: Merge CRL SOP GC30 and GC032 and follow the TCLP practice (use the method reference word for word and note CRL procedural deviations). There have been too many reference methods documented (see CA #7183 for a collection of incidents) in the course of 1 year. In order to prevent this situation from reoccurring, write the SOP exactly as the method reference and note deviations.

Noncompliance 02: The analysis date on the final report and LIMS (11/18/16) does not match the analysis date on the bench sheet (11/10/17).

Continuation of GC030 audit findings

Concern 01: During the SOP audit, a concern was witnessed while verifying the balance (#25) in use. When the balance software was pulled up, prepopulated fields appeared with the results (actual weight(s) record) from the last [balance] verification. The observed analyst overlapped the prepopulated information with the current standard weight results, printed, and filed it in a logbook. The balance software result (actual weight record(s)) fields should not be prepopulated in order to authentically and confidently document current results. Prepopulated results raise many questions in respects to tracking an original observation. PA #9282 has been initiated to address this observation.

Concern 02: Section 9.3.2 lacks instruction for documentation when the steps to add acid are performed, as well as some procedural clarification and reference citation corrections. See email message on 10/03/16 from AO to DL and MK, CC: GS.

Comment 01: SOP section 7.6.3.1 incorrectly references section 7.5.2.2 which doesn't exist. SOP section 8.4 references GEN013 for sample refrigeration preservation, but GEN013 does not contain the information because the sample preservation table was relocated elsewhere (SC folder in Qualtrax I believe) in Sept 2016. Perhaps document the Qualtrax ID number in case it gets relocated in the future.

MS026 – SVOA (Technology: GC)

Witnessing: No findings or comments
Technical Data Review: Pending (data not yet available). Any findings resulting from the pending data review will be attached as an appendix to this report, whenever it is available.